REMARKS

Applicant respectfully requests entry of the Amendment and reconsideration of the claims. New claims 18-29 have been added. Support can be found throughout the specification, including at page 6, lines 10-15; page 10, lines 13-22; and page 13, lines 10-26. No new matter has been added by the new claims. Claims 11-13 and 17-29 will be pending upon entry of this amendment. This amendment is filed concurrently with a Request for Continued Examination (RCE). Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Interview Summary

Applicant is grateful for the grant and time spent on a personal interview between Dr. Ronald A. Daignault and David Heller, Applicant's representatives, and Dr. Charlton, a consultant to DiaMedica (non-inventor), with Examiner Nancy Zhang and Supervisor Arden Marshall. First, the case law regarding kits was considered, and it was discussed whether or not "written instructions" could fill the roll of a second functional component. The Examiner invited Applicant to submit further written argument on this point.

The second issue discussed was whether or not a kit "prepared for sale" comprising a drug and written instructions would be patentable. The Examiner and her supervisor expressed interest in this argument, and again invited written arguments.

Thirdly, it was discussed whether or not a second functional component to a kit could comprise a "meal". Again, the Examiner and her supervisor expressed interest, and invited the submission of written comments.

Rejection Under 35 U.S.C. § 103(a)

The Examiner maintains the rejection of claims 11-13 and 17 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokkers-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576. To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference

teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

In an earlier office action, the Examiner acknowledged that these prior art references do not specifically disclose formulating the compositions into a kit with instructional material that is specified for oral administration of the nitric oxide donor and/or nitric oxide agonist compositions to ameliorate symptoms of insulin resistance. Thus it is respectfully submitted that, if it is determined that the instructional materials are a part of a kit, the 35 U.S.C. 103(a) rejection is rendered moot.

Kit Claims

In the response to the previously submitted arguments regarding kit claims, the Examiner stated that the claimed kits are unpatentable over the prior art, because of the compositions within the kit function equally effectively with or without the instructions. Thus the Examiner stated that *no functional relationship* exits between the instructions for use and the composition. The Examiner stated that if the compounds that make up the compositions in the claimed kits were administered to a patient, they would continue to exert a pharmaceutical effect. The Examiner stated that the claimed nitric oxide donor and/or nitric oxide agonists can function as active, effective drugs even in the absence of the instructional material.

Upon review of the cited case law, Applicant respectfully asserts that the Examiner is applying too high of a standard for functionality. *In Re Miller*, cited by the Examiner, clearly states that there is no requirement for a structural relationship between printed matter and other elements of a combination. The Patent Appeal Board in that case held that what is significant between elements of a claimed combination is not "the structural relationship but functional relationship".

The Examiner newly cites *In re Venezia* as standing for the proposition that kits are drawn to structural attributes of interrelated components parts, and not to activities that may or may not occur. With respect, the applicant respectfully disagrees. *In re Venezia* merely discusses "kits of interrelated parts", and does not stand for the proposition that kits must relate to structural attributes of interrelated component parts in order to patentable, as suggest by the Examiner.

The Examiner newly cites *In Re Haller* as standing for the proposition that the application of printed matter to old an article cannot render the article patentable. *In re Haller* concerns the labeling of an insecticide. *In re Haller* is distinguished from the present case in that, in the case of pharmaceutical administration, the instructions that specify how to administer the pharmaceutical, under what conditions, and for what ailments, is inherently functionally related to the product, since both the physician and patient require and rely on the instructions in administering a drug.

The Examiner again cites *In re Ngai* and *In re Gulack*. As previously pointed out in *Ngai* and *Gulack*, both the prior art and claimed invention contained instructional materials instructing on the claimed use. In contrast, none of the references cited by the Examiner disclose formulating the compositions in a kit with instructional material. None of the cited references, alone or in combination, teach or suggest formulating the compositions into a kit with instructions for administering the compositions to treat insulin resistance. None of the references, alone or in combination, provide a motivation for formulating the claimed structurally modified compositions into a kit with instructions for administering the compositions to ameliorate symptoms of insulin resistance. Reconsideration and allowance is respectfully requested.

With respect to the new claims, Applicant notes the following:

1. New claims 18-21 do not give rise to the issue of the instructions being functionally related to a composition.

2. New claims 22-25 introduce a new element that the composition is specifically prepared for sale as a pharmaceutical composition. As the Examiner will appreciate, the packaging of a kit as a pharmaceutical clearly and by law creates a necessary functional relationship between the pharmaceutical composition and the instructions. By law, and by necessity for use by a physician, pharmacist, and patient, instructions must accompany a composition prepared for sale as a pharmaceutical composition.

3. Claims 26-29 introduce the element of instructions that specify administering the composition with a meal. Instructions that specify administering the composition with a meal are functionally related to the product, since the kit claimed in claims 26-29 requires and relies on the instructions of administering the drug with a meal.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Summary

In view of the above remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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